Application Note

FOB Turbilatex, Vitros 5600, Ortho Clinical Diagnostics

(AN-Fb-Vitros 5600.EN rev 2019.05.27)

For *in vitro* diagnostic device
ENGLISH

General Information

Intended use:
FOB Turbilatex is a latex turbidimetric assay for the quantitative detection of human haemoglobin in human stool samples.
This assay is simple and widely applicable. Test results aid in a presumptive diagnosis of faecal occult blood (gastrointestinal bleeding).
For professional *in vitro* diagnostic use only.
FOB Turbilatex can be performed on every open chemistry analyser. Please follow the subsequent instructions in order to assure performance characteristics as describes in the instructions for use. This instruction has been validating by CerTest BIOTEC S.L Laboratories.
Additionally, please read the "Instructions for use" for instructions on operating and programming user defined test.

Reagents:

Materials provided by CerTest BIOTEC S.L.:

Reagents	Quantity	Cat. reference
Turbidimetric reagents (R1 & R2) 200 Det/kit	R1: 2 vials, 2x22 mL. R2: 1 vial, 1x13 mL.	TL-022FB01 TL-022FB02
Auxiliary Reagents	**Quantity**	**Cat. reference**
Calibration kit	Calibrator: 6 vials, 6x1 mL.	TL-022FB70, TL-022FB71, TL-022FB72, TL-022FB73, TL-022FB74, TL-022FB75
Controls kit	Control C1, 2 vials, 2x1 mL/vial. Control C2, 2 vials, 2x1 mL/vial.	TL-022FB08 TL-022FB09
Sample diluent kit	4 vials, 4x125 mL/vial	TL-022FB03E
Sample dilutions vials	1x2 mL/vial 1x2 mL/vial	MST-0005MF MST-0009F

Preparation of reagents:
R1 and R2 are ready to use.

Calibrators are ready to use.

Controls are ready to use

Storage and stability
Kit components must be stored at temperature indicated on the label. Do not freeze.

Reagents are stable up to the expiration date printed on the label, always considering that reagent containers must be properly closed to avoid any contamination, must be kept away from the sunlight and conserved at temperature indicated on the label of each reagent.

Specimen:
Collect enough quantity of human stool samples. These samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC) for 3 days prior to testing. Homogenise stool samples as thoroughly as possible prior to preparation.

The sample dilution vial with diluted sample can be stored for 7 days in the refrigerator (2-8ºC) prior to testing.

Use FOB Turbilatex stool collection tubes for sample collections described the instructions for use.

Assay procedure

Application parameter set up:
Specific analyzers settings for FOB Turbilatex must be programmed onto the analyzer, see below. For instructions, consult the Vitros 5600 (Ortho Clinical Diagnostics) analyzer manual and instructions for use provided with the kit.

Loading of reagents:
Load reagents according to the Vitros 5600 (Ortho Clinical Diagnostics) analyzer manual.

Calibration curve establishment:
A 6-points calibration curve can be established in Vitros 5600 (Ortho Clinical Diagnostics) analyzer. For instructions consult analyzer manual.

Calibration stability:
Calibrate the system at least once a month is extremely recommended. Recalibrate the system when reagent lot is change or when the controls are out of the assigned range given in the control label and CoA.

QC controls:
FOB Turbilatex controls C1 and C2 must be assayed each day before running patient fecal sample extract to validate the calibration curve. The controls have assigned value ranges indicated on the label and certificate of analysis supplied. The control measurements must be within the indicated value range to obtain valid results for patient fecal extract. If the control values are out of range, follow next procedures: 1) Repeat QC control measurement, 2) Repeat calibration measurement.

Results:
The results are evaluated automatically by the analyzer and presented in ng/mL.

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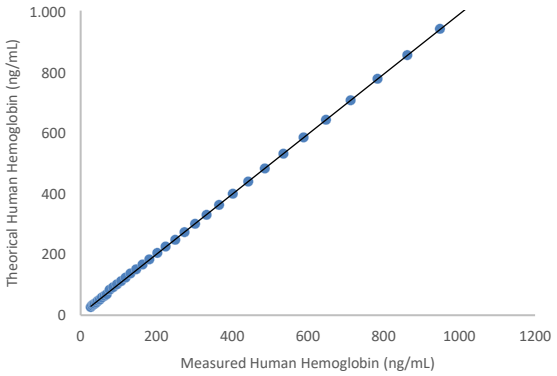
Performance characteristics

The following results have been obtained during the validation of FOB Turbilatex on the Vitros 5600 (Ortho Clinical Diagnostics) analyzer.

Linearity:
FOB Turbilatex on Vitros 5600 (Ortho Clinical Diagnostics) instrument using calibrator kit is linear in the calibration range of 0-1000 ng/mL.



Measuring range:
FOB Turbilatex assay measuring range is 20-1000 ng/mL on the Vitros 5600 (Ortho Clinical Diagnostics) analyser. Samples higher concentrated than 1000 ng/mL must be diluted for proper quantification by the user, using additional sample buffer.

Prozone effect
Using the reported parameters, no hook effect was observed up to 8000 ng/mL. Samples with Haemoglobin concentration of 16000 ng/mL give a typical positive result >1000 ng/mL.

Detection limit
Limit of detection (LOD): 15 ng/mL. The lower limit of detection of FOB Turbilatex was determined on 20 samples and 2 sample replicates as the mean value + 2·SD.

Limit of quantification (LOQ): 20 ng/mL. The lower limit of quantification is defined as the lowest actual amount of analysis that can be reliably detected; imprecision is < 20% as CV% on the Vitros 5600 (Ortho Clinical Diagnostics) instrument.

Precision
FOB Turbilatex was tested with three different controls levels.

	Low (50 ng/mL)	Medium (100 ng/mL)	High (500 ng/mL)
N	20	20	20
Mean (ng/mL)	52.1	103.6	504.8
SD (ng/mL)	3.1	6.4	10.3
CV (%)	5.9	6.2	2.0

Method comparison

Results obtained with FOB Turbilatex on the Vitros 5600 (Ortho Clinical Diagnostics) instrument were compared with those obtained with EIKEN FOB Latex.

	Sensitivity	Specificity
FOB Turbilatex vs EIKEN FOB Latex	96%	>99%

Shipping damage

Please notify your distributor, it this product was received damaged.

Symbols key

IVD	For *in vitro* diagnostic use only		Keep dry
	Consult instructions for use		Temperature limitation
REF	Catalogue number	LOT	Lot number
	Use by		Manufacturer
Σ n	Contains sufficient for <n> test	DIL	Sample diluent
	Keep out of the sunlight		

Manufacturer

CERTEST BIOTEC

Pol. Industrial Río Gállego II,Calle J, Nº 1, 50840,
San Mateo de Gállego, Zaragoza (SPAIN)
www.certest.es

NOTES

Please refer to the instructions for use for the detailed information about the test on the following:
Synthesis; Principle; Precautions; Reagents; Specimen collection; Interpretation of results.

Vitros 5600 (Ortho Clinical Diagnostics) /Application parameters

ASSAY PARAMETERS	
Std. No	6
R1	200 µL
Sample	20 µL
R2	55 µL
Others	NA
Reaction mode	Endpoint
Primary wavelength	510 nm
Secondary wavelength	None
Direction	Increase
Reagent blank lecture	After R2 addition
Final lecture	294 s after blank lecture
Reaction time	10 min
Linear range	0-1000 ng/ml
CALIBRATION	
Calibration Method	Linear
Calibration set	6 calibrators
Blank	Calibrator 1 (0 ng/ml)
Calibrator 1	Calibrator 2 (50 ng/ml)
Calibrator 2	Calibrator 3 (100 ng/ml)
Calibrator 3	Calibrator 4 (250 ng/ml)
Calibrator 4	Calibrator 5 (500 ng/ml)
Calibrator 5	Calibrator 6 (1000 ng/ml)
STEPS	
Addition R1	
Addition Sample	
Incubation	90 s
Addition R2	
Blank Lecture	
Incubation	300 s
Final lecture	

Model: 2PT R1-S-R2

Measure method: Speed of 2 points. **PROTOCOL**	
Reagent 1	200 µl
Incubation	0.0 s
Sample	20 µl
Incubation	76.0 s
Reagent 2	55 µl
Incubation	0.0 s
Lecture	510 nm
Incubation	294.5 s
Lecture	510 nm